DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 9, 2015

Invacare Corporation
Doug Uelmen, Sr VP, QA & RA
One Invacare Way
PO Box 4028
Elyria, OH 44036-2125

Re: K141783
Trade/Device Name: Invacare® TDX® SP2 Power Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: December 10, 2014
Received: December 11, 2014

Dear Mr. Doug Uelmen,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141783

Device Name
Invacare® TDX SP2® Power Wheelchair

Indications for Use *(Describe)*
The intended use of the device is to provide mobility to persons limited to a sitting position.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Device Proprietary Name:	Invacare® TDX® SP2 Power Wheelchair
Common Name:	Powered Wheelchair
Classification Regulation:	21 CFR, 890.3860
Product Code:	ITI
Device Class:	II
Submitter's Name:	Invacare, Corp.
Address:	One Invacare Way P.O. Box 4028 Elyria, Ohio 44036-2125
Contact Person:	Doug Uelmen
Telephone Number:	(440) 329-6619
Fax Number:	(440) 329-6975
Date Summary Prepared:	December 26, 2014

Device Description

The Invacare® TDX® SP2 Power Wheelchair is a battery-powered, motor-driven device controlled by the MK6i™ (MK6i) electronics platform. The intended use of the device is to provide mobility to persons limited to a sitting position. Use environments include, but are not limited to, the user's home, assisted living facilities, nursing homes, vocational settings, health care facilities and outdoors on firm terrain. Adult seating has a weight limit of 300 lbs. and junior seating has a weight limit of 165 lbs.

The subject device is the next generation of the TDX Power Wheelchair with:

- Enhanced suspension and stability;
- Additional back and arm types as well as leg rest types; and
- A new controller, the MK6i, which incorporates upgraded software.

The Invacare® TDX® SP2 Power Wheelchair includes an upgraded Gyroscope Module (G-Trac Control Module) and Enhanced SureStep® Suspension with Stability Lock.

Purpose of Submission

The Invacare® TDX® SP2 Power Wheelchair is a new device and represents the next generation of power wheelchairs in the Invacare® TDX® Power Wheelchair product family.

Indication for Use

The indication for use of the Invacare® TDX® SP2 Power Wheelchair is to provide mobility to persons limited to a sitting position.

Predicate Devices

The predicate device is the Storm TDX® Power Wheelchair, which was cleared under K023589 on November 19, 2002. The Storm TDX® Power Wheelchair also includes the G-Trac Control Module. This technology is similar to the Gyroscope Control technology that was cleared on the Storm Series Power 9000 and Tiger Power Wheelchairs, cleared under K993413 on December 15, 1999.

The previously cleared and subject power wheelchair configurations are similar in that both wheelchairs provide the user with several joystick options, power seating and controllers that are fully programmable for performance characteristics such as forward speed, turning speed, forward and reverse acceleration, braking, torque and others.

The previously cleared and subject gyroscope controllers help to maintain a straight course over uneven terrain by sensing the direction and feeding it back to the controller for direct closed-loop feedback control of the chair.

Technological Characteristics/Substantial Equivalence

The Invacare® TDX® SP2 Power Wheelchair has the same indication for use, is manufactured from the same or similar materials and incorporates similar technological characteristics as the predicate device.

The table below provides a comparison of the subject device to the predicate device.

Comparison Table

	Predicate Device	Subject Device
Brand Name	Storm TDX® Power Wheelchair	Invacare® TDX® SP2 Power Wheelchair
Manufacturer	Invacare , Corp.	Invacare, Corp.
510(k) Number	K023589	K141283
Intended Use	The intended use is to provide mobility to persons limited to a sitting position.	The intended use is to provide mobility to persons limited to a sitting position.

Comparison Table (continued)

	Predicate Device	Subject Device
Power Seating Configurations	Power seating with tilt, elevate and recline as well as power leg rests	Power seating with tilt, elevate and recline as well as power leg rests
Driver Controls	Joysticks, head array and sip-n-puff	Joysticks, head array and sip-n-puff
Weight Capacity	250 lbs., 300 lbs. and 400 lbs. depending on model	165 lbs. (Junior seating) 300 lbs. (Adult seating)
Maximum Speed	4.5-7.5 mph	5.8 mph
Range	22NF batteries: >12 miles GP24 batteries: >15 miles	22NF batteries: >12 miles GP24 batteries: >15 miles
Seat Widths	12”-24”	12”-24”
Seat Depths	12”-22”	12”-22”
Seat Types	Adjustable back; van; recline; tilt/recline, tilt/recline/elevate; tilt, elevate; elevate	Adjustable back; van; recline; tilt/recline, tilt/recline/elevate; tilt, elevate; elevate
Caster Size	6”x 2”	6”x 2”
Upholstery	Cloth or vinyl	Cloth or vinyl
Arm Types	Flip back; fixed or adjustable height; desk or full length	Flip back; fixed or adjustable height; cantilever—desk or full length
Overall Length without Leg Rests	35.25”	35.5”
Overall Width with 18” wide ASBA (excluding joystick)	25.5”	25.5”
Drive Wheel Size	14”x 3”	14”x 3”
Drive Wheel Frame Material	Aluminum	Aluminum
Base Weight with GP24 Batteries	240-310 lbs. depending on model	264 lbs.
Total Weight (Base and Seat)	TDX3 = 238 lbs. TDX4 = 256 lbs. TDX 5 = 313 lbs.	291 lbs. – 425 lbs. (depending on seat type/configuration
Chargers	8-amp off board charger (110 or 220V)	8-amp off board charger (110 or 220V)
Motor	Gearless, Brushless	Not applicable
Motor	4-pole	4-pole
Motor	2-pole	Not applicable
Stability Lock Mechanism	Gear teeth to gear teeth	Internal locking valve mechanism in gas cylinder
Gyroscope Control Module	Ceramic piezoelectric element based gyroscope controller	Spring support polysilicon gyro resonating mass controller
Suspension	SureStep® Suspension	Enhanced SureStep® Suspension

Comparison Table (continued)

	Predicate Device	Subject Device
Electronics	MKV	MK6i
Miscellaneous Accessories	Wheel locks O2 Holder (ASBA only)	Wheel locks O2 Holder (ASBA only)

Performance Data

The Invacare® TDX® SP2 Power Wheelchair has been evaluated through non-clinical performance testing and is in compliance with the following test standards:

- ANSI/RESNA WC-1:2009 Section 1: Determination of Static Stability
- ANSI/RESNA WC-2:2009 Section 2: Determination of Dynamic Stability
- ANSI/RESNA WC-2:2009 Section 3: Determination of Effectiveness of Brakes
- ANSI/RESNA WC-2:2009 Section 4: Energy Consumption for Determination of Theoretical Distance
- ANSI/RESNA WC-1:2009 Section 5: Determination of Dimensions, Mass and Maneuvering Space
- ANSI/RESNA WC-2:2009 Section 6: Determination of Maximum Speed, Acceleration and Deceleration
- ANSI/RESNA WC-1:2009 Section 7: Method of Measurement of Seating and Wheel Dimensions
- ANSI/RESNA WC-1:2009 Section 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths
- ANSI/RESNA WC-2:2009 Section 9: Climatic Tests
- ANSI/RESNA WC-2:2009 Section 10: Determination of Obstacle Climbing
- ANSI/RESNA WC-1:2009 Section 14: Power and Control Systems Requirements and Test Methods
- ANSI/RESNA WC-1:2009 Section 15: Requirements for Information Disclosure, Documentation and Labeling
- ANSI/RESNA WC-1:2009 Section 16: Resistance to Ignition of Upholstered Parts—Requirements and Test Methods
- ANSI/RESNA WC-2:2009 Section 21: Requirements and Test Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Motorized Scooters
- ISO 10993 Biocompatibility Testing

Conclusion

The proposed TDX SP2 Power Wheelchair has the same indication for use as the predicate TDX Power Wheelchair. There are technological differences between the subject and predicate device however, the results of performance testing demonstrate that these differences do not raise any new questions of safety or effectiveness compared to other similar power wheelchairs currently marketed.

The conclusion drawn from the test data is that the TDX SP2 Power Wheelchair is as safe and effective as the predicate device, has the same intended use as the predicate, performs similarly to other legally marketed power wheelchairs indicated for providing mobility to persons limited to a sitting position and does not raise any new issues of safety or effectiveness.